

**VIA HAND DELIVERY**

June 9, 2005

Food and Drug Administration  
Office of Nutritional Products, Labeling  
And Dietary Supplements (HFS-800)  
5100 Paint Branch Parkway  
College Park, Maryland 20740

*Brenda Adams*  
*6-13-05*  
*12:48 pm*



7361 Calhoun Place,  
Suite 500  
Rockville, Maryland 20855-2765  
301.838.3120  
fax: 301.838.3182

RE: Petition for Qualified Health Claim for Green Tea and Reduction  
of a Number of Risk Factors Associated with Cardiovascular  
Disease

Dear Sir/Madame:

Enclosed please find an original and one copy of a petition for a Qualified Health Claim for Green Tea and Reduction of a Number of Risk Factors Associated with Cardiovascular Disease.

AAC Consulting Group is submitting this petition pursuant to Section 403(r)(4) and 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act on behalf of Ito En, Ltd and Ito En (North America), Inc., 45 Main Street, Suite 3A, Brooklyn, New York 11201, USA. Petitioner respectfully proposes that the qualified health claim be approved for labeling of the conventional foods or dietary supplements containing Green Tea as follows:

**Daily consumption of at least 5 fluid ounces (150 mL) of green tea as a source of catechins may reduce a number of risk factors associated with cardiovascular disease. FDA has determined that the evidence is supportive, but not conclusive, for this claim. (Green tea provides 125 mg catechins per serving when brewed from tea and 125 mg catechins as a pre-prepared beverage).**

We are waiving the right to a review under the significant scientific agreement standard and request that the petition be reviewed under the interim procedures for a qualified health claim. We believe that the FDA's qualified health claim program is a positive step, which can greatly benefit the health of consumers in making informed decisions regarding their diet.

2005Q-0297

QHC 1

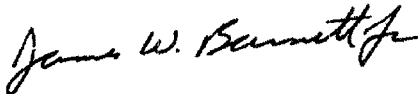
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An independent panel of recognized experts reviewed the information in the enclosed petition and concluded:

1. That the scientific information presented here supports the proposed qualified health claim; and,
2. that the document is a reasonable and representative interpretation of the scientific literature in support of the potential reduction of a number of risk factors associated with cardiovascular disease.

As presented in the scientific summary, the majority of evidence from publicly available scientific studies supports the conclusion that an intake of greater than 1 cup of green tea per day, providing at the minimum 250 mg/day of the catechins present as components of green tea, would have a positive effect on a number of risk factors associated with cardiovascular disease and would either reduce or delay its onset. If you have any questions, please contact me or Stanley M. Tarka, Jr., Ph.D., at 717-243-9216..

Sincerely,



James W. Barnett, Jr., Ph.D., D.A.P.T.  
Director  
Food, Dietary Supplement & Cosmetic Consulting

Enclosure

QUALIFIED HEALTH CLAIM PETITION FOR  
GREEN TEA AND REDUCTION OF A NUMBER  
OF RISK FACTORS ASSOCIATED WITH  
CARDIOVASCULAR DISEASE

SUBMITTED TO THE FOOD AND DRUG  
ADMINISTRATION

June 9, 2005

PETITIONER:

ITO EN, LTD  
47-10 Honmachi 2 chome  
Shibuya-ku  
151-8550 Tokyo  
Japan

ITO EN (NORTH AMERICA), Inc.  
45 Main Street, Suite 3A  
Brooklyn, New York 11201  
USA

Submitted by:  
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